This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

4/17/92

SMDA CHANGES

PMA MANUAL INSERT

Since this booklet was published, Congress has amended the Federal Food, Drug, and Cosmetic (FD&C) Act, in the Safe Medical Devices Act (SMDA) of 1990. The SMDA was signed into law on November 28, 1990. This attachment contains a brief summary of the new provisions which most specifically pertain to Premarket Approval not included elsewhere in this publication. An updated edition of the Premarket Approval Manual will be issued in the near future. Meanwhile, more information on SMDA can be found in a booklet available from the Division of Small Manufacturers Assistance, "Highlights of the Safe Medical Devices Act of 1990 (Public Law 101-629)."

NEW REQUIREMENTS IN BRIEF THAT MOST SPECIFICALLY PERTAIN TO PREMARKET APPROVAL

Use of Premarket Approval (PMA) Data

- Information contained in a PMA application, including clinical and preclinical tests -- but excluding descriptions of methods of manufacture and product composition -- that demonstrates safety and effectiveness shall be available for use by the FDA one year after the approval of the original PMA application for the fourth device of a kind. This information can be used by FDA in approving other PMA applications, establishing a performance standard, or in reclassification activities.

- At the time of approval of the PMA application for the fourth device of a kind, FDA shall publish a notice in the Federal Register identifying the four devices of a kind and the date on which data will be available for use by the FDA.

- Any challenge to the order authorizing use of PMA data must be made within 30 days after publication of the notice.

Temporary Suspension of Premarket Approval

If, after providing an opportunity for an informal hearing regarding the proposed withdrawal of PMA approval, FDA determines there is a reasonable probability that continued distribution of a PMA-approved device would cause serous adverse health consequences or death, FDA shall by order temporarily suspend the PMA and in cases where there is sufficient grounds, proceed expeditiously to withdraw the PMA approval.

Reclassification of Class III Preamendment Devices

- Upon issuance of an order by FDA, on or before December 1, 1995, manufacturers of Class III preamendment devices shall submit to FDA a summary of, and citation to, any information known or otherwise available to the manufacturer concerning the device, including adverse safety and effectiveness information. FDA may also require submission of the adverse safety and effectiveness data from which the summary was derived, if available to the manufacturer.

- After reviewing these data, FDA shall determine whether such devices remain in Class III or be down classified into Class II or Class I; and shall issue proposed regulations of such action for comment.

- By December 1, 1995, FDA shall issue final regulations for reclassifying Class III preamendment devices or retaining them in Class III.

- For preamendment devices retained in Class III, FDA shall -- not later that 12 months after the effective date of the final regulation -- establish a schedule for issuance of regulations requiring submission of PMAs.

Transitional Devices

- Before December 1, 1991, FDA shall by order require manufacturers of Class III transitional devices to submit a summary of, and citation to, any information including adverse safety and effectiveness information, known or available to the manufacturer. This order was published in the Federal Register of November 14, 1991.

- Before December 1, 1992, FDA shall determine whether Class III transitional devices will remain in Class III or be down classified into Class I or Class II. This period can be extended by FDA for 1 year.

- If FDA has not made a determination for daily wear soft or daily wear nonhydrophylic plastic contact lenses within 24 months of the date of enactment, it must issue an order reclassifying these lenses into Class II. This period can be extended by FDA for an additional year.

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